DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124223
Facility ID:142505
Inspection ID #1425050006

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

01-BLT-33

June 13, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Laurie Fajardo, Director Breast Imaging
Johns Hopkins Breast Imaging
601 North Caroline Street
Baltimore, Maryland 21287

Dear Dr. Fajardo:

A representative from the State of Maryland under contract to the Food and Drug Administration (FDA) inspected your facility on May 30, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Your facility failed to document that phantom image testing was performed for the weeks of 9/24/00, 10/01/00, 10/22/00, 11/05/00, 11/12/00, and 11/26/00 for the [redacted] mammography unit located in room #1.**

- **Your facility failed to document that phantom image testing was performed for the weeks of 9/17/00, 10/01/00, 10/22/00, 11/05/00, 11/12/00, and 11/26/00 for the [redacted] mammography unit located in room #2.**

- **Your facility failed to document that phantom image testing was performed for the weeks of 9/17/00, 9/24/00, 10/01/00, 11/05/00, 11/12/00, 11/19/00, and 11/26/00 for the [redacted] mammography unit located in room #3.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they identify a failure to comply with a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to perform corrective actions before further patient exams for failing phantom image tests performed on the [redacted] mammography unit located in room #1 for the following dates: 03/09/01, 3/16/01, 04/28/00, and 05/04/01.**

- **Your facility failed to perform corrective actions before further patient exams for failing phantom image tests performed on the [redacted] mammography unit located in room #2 for the following dates: 06/02/00, 06/09/00, 6/16/00, 6/23/00, 6/30/00, 7/7/00, 7/14/00, 7/21/00, 7/28/00, 8/3/00, 8/11/00, 8/18/00, 8/25/00, 9/1/00, 10/13/00, 4/06/01, 4/28/01, 5/4/01 and 5/14/01.**

- **Your facility failed to perform corrective actions before further patient exams for failing phantom image tests performed on the [redacted] mammography unit located in room #3 for the following dates: 06/23/00, 6/30/00, 7/7/00, 7/14/00,7/21/00, 7/28/00, 8/4/00, 8/11/00, 8/18/00, 9/8/00, 9/15/00, 9/22/00, 9/29/00, 10/6/00, 10/13/00, 10/20/00, 10/27/00, 11/3/00, 11/10/00, to 11/17/00, 1/29/01, 3/2/01, 3/23/01, 5/4/01, 5/14/01.**

- **Your facility failed to perform an annual medical outcome analysis for the facility as a whole, and for each individual radiologist.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.

- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Mr. Gerald Miller, Compliance Officer, Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, MD 21201-2199.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug